



Docket No.: HUI-041DV
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Laurie H. Glimcher *et al.*

Application No.: 10/643581

Confirmation No.: 3956

Filed: August 19, 2003

Art Unit: 1633

For: METHODS AND COMPOSITIONS
RELATING TO MODULATION OF
HEPATOCYTE GROWTH, PLASMA CELL
DIFFERENTIATION OR T CELL SUBSET
ACTIVITY BY MODULATION OF XBP-1
ACTIVITY

Examiner: Q.J. Li

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT (IDS)

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

For the Examiner's convenience in reviewing this continuation application, Applicants submit a consolidated PTO Form SB/08, listing all references cited during the prosecution of the parent application. References B1-B2, C1-C60 were previously cited and submitted to the Office in U.S. Application Serial No. 09/753,346, filed December 29, 2000 now U.S. Patent 6,632,608 B2 (Atty. Docket No. HUI-041), of which this application is a divisional and to which this

application claims priority. In accordance with 37 CFR §1.98(d), these references are not enclosed herewith, but will be provided upon request. In addition, this Information Disclosure Statement presents reference C61, not previously submitted to the Office, which is enclosed herewith in accordance with 37 CFR §1.97. Reference C61 is a European Search Report issued by the European Patent Office March 17, 2006 in related application EP 05 01 3817.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.


It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. HUI-041DV.

Dated: June 14, 2006

MEW/DLN/mch

Respectfully submitted,

By 
Megan E. Williams
Registration No.: 43,270
LAHIVE & COCKFIELD, LLP
28 State Street
Boston, Massachusetts 02109
(617) 227-7400
(617) 742-4214 (Fax)
Attorney/Agent For Applicant



PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number	10/643581-Conf. #3956
Filing Date	August 19, 2003
First Named Inventor	Laurie H. GLIMCHER
Art Unit	1633
Examiner Name	Q.J. Li
Attorney Docket Number	HUI-041DV

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	B1	WO-97/39721-A2	10-30-1997	President and Fellows of Harvard College		
	B2	EP-0857780-A1	08-12-1998	Sumitomo Electric Industries, Ltd.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	Andersson, L-O. "Pharmacology of apolipoprotein A-I" <i>Curr. Opin. Lipidol.</i> 8:225-228 (1997)	
	C2	Bancroft, A.J. et al. "Cytokine Production in BALB/c Mice Immunized with Radiation Attenuated Third Stage Larvae of the Filarial Nematode, <i>Brugia pahangi</i> " <i>J. Immunol.</i> 150(4):1395-1402 (Feb 15 1993)	
	C3	Beg, A.A. et al. "Embryonic lethality and liver degeneration in mice lacking the RelA component of NF- κ B" <i>Nature</i> 376:167-170 (Jul 13 1995)	
	C4	Chen, B.P. et al. "Analysis of ATF3, a transcription factor induced by physiological stresses and modulated by gadd153/Chop10" <i>Mol. Cell Biol.</i> 16:1157-1168 (1996)	
	C5	Chen, C. et al. "In Vitro Induction of T Cell Anergy by Blocking B7 and Early T Cell Costimulatory Molecule ETC-1/B7-2" <i>Immunity</i> 1:147-154 (May 1994)	
	C6	Chen, H. et al. "Regulation and Activities of α -Fetoprotein" <i>Critical Reviews in Eukaryotic Gene Expression</i> 7(1&2):11-41 (1997)	
	C7	Clauss, I.M. et al. "In Situ Hybridization Studies Suggest a Role for the Basic Region-Leucine Zipper Protein hXBP-1 in Exocrine Gland and Skeletal Development During Mouse Embryogenesis" <i>Dev. Dynamics</i> 197:146-156 (1993)	
	C8	Clerici, M. et al. "A Th1 \rightarrow Th2 switch is a critical step in the etiology of HIV infection" <i>Immunol. Today</i> 14(3):107-111 (1993)	
	C9	Dallman, M.J. "Cytokines and transplantation: Th1/Th2 regulation of the immune response to solid organ transplants in the adult" <i>Curr. Opin. Immunol.</i> 7:632-638 (1995)	
	C10	Else, K.J. et al. "Cytokine-mediated Regulation of Chronic Intestinal Helminth Infection" <i>J. Exp. Med.</i> 179:347-351 (Jan 1994)	
	C11	Fässler, R. et al. "Consequences of lack of β 1 integrin gene expression in mice" <i>Genes & Development</i> 9:1896-1908 (1995)	
	C12	Fauci, A.S. "The Human Immunodeficiency Virus: Infectivity and Mechanisms of Pathogenesis" <i>Science</i> 239:617-623 (Feb 5 1988)	

Examiner Signature	Date Considered
-----------------------	--------------------

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/643581-Conf. #3956
				Filing Date	August 19, 2003
				First Named Inventor	Laurie H. GLIMCHER
				Art Unit	1633
				Examiner Name	Q.J. Li
Sheet	2	of	4	Attorney Docket Number	HUI-041DV

C13	Fowler, D.H. et al. "Donor CD4-Enriched Cells of Th2 Cytokine Phenotype Regulate Graft-Versus-Host Disease Without Impairing Allogeneic Engraftment in Sublethally Irradiated Mice" <i>Blood</i> 84(10):3540-3549 (Nov 15 1994)
C14	Fowler, D.H. et al. "Donor Lymphoid Cells of Th2 Cytokine Phenotype Reduce Lethal Graft Versus Host Disease and Facilitate Fully Allogeneic Cell Transfers in Sublethally Irradiated Mice" <i>Advances in Bone Marrow Purging and Processing: Fourth International Symposium. Prog. Clin. Biol. Res.</i> 389:533-540 (1994)
C15	Gabay, C. et al. "Acute-Phase Proteins and Other Systemic Responses to Inflammation" <i>New England Journal of Medicine</i> 340(6):448-454 (Feb 11 1999)
C16	GenBank GI:4827058 for X-box binding protein 1; X-box-binding protein-1 [Homo sapiens]
C17	GenBank Accession No. A36299 for transcription factor hXBP-1 - human
C18	GenBank Accession No. BAA82600 for hepatocarcinogenesis-related transcription factor (HTF) [Rattus norvegicus]
C19	GenBank Accession No. CAA39149 for TREB protein [Homo sapiens]
C20	GenBank Accession No. P17861 for X BOX BINDING PROTEIN-1 (XBP-1) (TREB5 PROTEIN)
C21	Gorczyński, R.M. et al. "Interleukin 12 in Combination With Anti-Interleukin 10 Reverses Graft Prolongation After Portal Venous Immunization" <i>Transplantation</i> 60(11):1337-1341 (Dec 15 1995)
C22	Grzych, J.-M. et al. "Egg Deposition is the Major Stimulus for the Production of Th2 Cytokines in Murine Schistosomiasis Mansonii" <i>J. Immunol.</i> 146(4):1322-1327 (Feb 15 1991)
C23	Gualdi, R. et al. "Hepatic specification of the gut endoderm in vitro: cell signaling and transcription control" <i>Genes Dev.</i> 10:1670-1682 (1996)
C24	Günes, C. et al. "Embryonic lethality and liver degeneration in mice lacking the metal-responsive transcriptional activator MTF-1" <i>EMBO J.</i> 17:2846-2854 (1998)
C25	Hentsch, B. et al. "Hlx homeo box gene is essential for an inductive tissue interaction that drives expansion of embryonic liver and gut" <i>Genes Dev.</i> 10:70-79 (1996)
C26	Hirsch, E. et al. "Impaired migration but not differentiation of haematopoietic stem cells in the absence of β_1 integrins" <i>Nature</i> 380:171-175 (Mar 14 1996)
C27	Jacks, T. et al. "Effects of an Rb mutation in the mouse" <i>Nature</i> 359:295-300 (Sep 24 1992)
C28	Khoury, S.J. et al. "Oral Tolerance to Myelin Basic Protein and Natural Recovery from Experimental Autoimmune Encephalomyelitis Are Associated with Downregulation of Inflammatory Cytokines and Differential Upregulation of Transforming Growth Factor β , Interleukin 4, and Prostaglandin E Expression in the Brain" <i>J. Exp. Med.</i> 176:1355-1364 (Nov 1992)
C29	Kishimoto, T. et al. "Enhanced Expression of a New Class of Liver-enriched b-Zip Transcription Factors, Hepatocarcinogenesis-related Transcription Factor, in Hepatocellular Carcinomas of Rats and Humans" <i>Cell Growth & Differentiation</i> 9:337-344 (April 1998)
C30	Kishimoto, T. et al. "HTF: A B-Zip Transcription Factor That Is Closely Related to the Human XBP/TREB5 and Is Activated by Hepatocellular Carcinoma in Rats" <i>Biochem. Biophys. Res. Commun.</i> 223:746-751 (1996)
C31	Kullberg, M.C. et al. "Infection With <i>Schistosoma mansoni</i> Alters Th1/Th2 Cytokine Responses to a Non-Parasite Antigen" <i>J. Immunol.</i> 148(10):3264-3270 (May 15 1992)
C32	Lee, E. Y.-H. P. et al. "Mice deficient for Rb are nonviable and show defects in neurogenesis and haematopoiesis" <i>Nature</i> 359:288-294 (Sep 24 1992)
C33	Levy, A.E. et al. "Administration of Ingraft Interleukin-4 Prolongs Cardiac Allograft Survival in Rats Treated With Donor-specific Transfusion/Cyclosporine" <i>Transplantation</i> 60:405-406 (Sep 15 1995)
C34	Liou, H.-C. et al. "A New Member of the Leucine Zipper Class of Proteins That Binds to the HLA DR α Promoter" <i>Science</i> 247:1581-1584 (Mar 30 1990)

Examiner Signature	Date Considered
--------------------	-----------------

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/643581-Conf. #3956
				Filing Date	August 19, 2003
				First Named Inventor	Laurie H. GLIMCHER
				Art Unit	1633
				Examiner Name	Q.J. Li
Sheet	3	of	4	Attorney Docket Number	HUI-041DV

C35	Locksley, R.M. et al. "Helper T-cell subsets in mouse leishmaniasis: induction, expansion and effector function" <i>Immunoparasitology Today</i> 1:A58-A61 (1992)
C36	Maeda, H. et al. "Adoptive transfer of a T _H 2-like cell line prolongs MHC class II antigen disparate skin allograft survival in the mouse" <i>International Immunology</i> 6(6):855-862 (1994)
C37	Maekawa, T. et al. "Mouse ATF-2 null mutants display features of a severe type of meconium aspiration syndrome" <i>J. Biol. Chem.</i> 274(25):17813-17819 (Jun 18 1999)
C38	Mucenski, M.L. et al. "A Functional c-myc Gene Is Required for Normal Murine Fetal Hepatic Hematopoiesis" <i>Cell</i> 65:677-689 (May 17 1991)
C39	Ono, S.J. et al. "Human X-box-binding protein 1 is required for the transcription of a subset of human class II major histocompatibility genes and forms a heterodimer with c-fos" <i>Proc. Natl. Acad. Sci. USA</i> 88:4309-4312 (May 1991)
C40	Paul, W.E. et al. "Lymphocyte Responses and Cytokines" <i>Cell</i> 76:241-251 (Jan 28 1994)
C41	Pearce, E.J. et al. "Downregulation of Th1 Cytokine Production Accompanies Induction of Th2 Responses by a Parasitic Helminth, <i>Schistosoma mansoni</i> " <i>J. Exp. Med.</i> 173:159-166 (Jan 1991)
C42	Pearlman, E. et al. "Induction of Murine T-Helper-Cell Responses to the Filarial Nematode <i>Brugia malayi</i> " <i>Infection and Immunity</i> 61(3):1105-1112 (Mar 1993)
C43	Pisa, P. et al. "Selective expression of interleukin 10, interferon γ , and granulocyte-macrophage colony-stimulating factor in ovarian cancer biopsies" <i>Proc. Natl. Acad. Sci. USA</i> 89:7708-7712 (Aug 1992)
C44	Rapoport, M.J. et al. "Interleukin 4 Reverses T Cell Proliferative Unresponsiveness and Prevents the Onset of diabetes in Nonobese Diabetic Mice" <i>J. Exp. Med.</i> 178:87-99 (Jul 1993)
C45	Reimold et al. "Transcription Factor B Cell Lineage-specific Activator Protein Regulates the Gene for Human X-Box Binding Protein 1" <i>J. Exp. Med.</i> 183:393-401 (Feb 1996)
C46	Reimold et al. "Chondrodysplasia and neurological abnormalities in ATF-2-deficient mice" <i>Nature</i> 379:262-265 (Jan 18 1996)
C47	Reimold, A. et al. "Control of Terminal B Cell Differentiation by Transcription Factor XBP-1" <i>Arthritis & Rheumatism</i> 42(9 Suppl.):S58 (1999)
C48	Reimold, A.M. et al. "An essential role in liver development for transcription factor XBP-1" <i>Genes & Development</i> 14:152-157 (2000)
C49	Rudolph, D. et al. "Impaired fetal T cell development and perinatal lethality in mice lacking the cAMP response element binding protein" <i>Proc Natl Acad Sci U S A.</i> 95(8):4481-4486 (Apr 14 1998)
C50	Schmidt, C. et al. "Scatter factor/hepatocyte growth factor is essential for liver development" <i>Nature</i> 373:699-702 (Feb 23 1995)
C51	Servillo, G. et al. "Transcription factor CREM coordinates the timing of hepatocyte proliferation in the regenerating liver" <i>Genes Dev.</i> 12(23):3639-3643 (Dec 1 1998)
C52	Shearer, G.M. et al. "T helper cell immune dysfunction in asymptomatic, HIV-1-seropositive individuals: the role of TH1-TH2 cross-regulation" <i>Chem. Immunol.</i> 54:21-43 (1992)
C53	Simon, A.K. et al. "Divergent T-cell cytokine patterns in inflammatory arthritis" <i>Proc. Natl. Acad. Sci. USA</i> 91:8562-8566 (Aug 1994)
C54	Takeuchi, T. et al. "Heart Allografts in Murine Systems. The Differential Activation of TH2-Like Effector Cells in Peripheral Tolerance" <i>Transplantation</i> 53(6):1281-1291 (Jun 1992)
C55	Taub, R. "Transcriptional control of liver regeneration" <i>FASEB J.</i> 10:413-427 (1996)
C56	Thai, N.L. et al. "Cytokine mRNA Profiles in Mouse Orthotopic Liver Transplantation" <i>Transplantation</i> 59(2):274-281 (Jan 27 1995)
C57	Tzakis, A.G. et al. "Early Tolerance in Pediatric Liver Allograft Recipients" <i>J. Pediatr. Surg.</i> 29(6):754-756 (Jun 1994)
C58	Uehara, Y. et al. "Placental defect and embryonic lethality in mice lacking hepatocyte growth factor/scatter factor" <i>Nature</i> 373:702-705 (Feb 23 1995)

Examiner Signature	Date Considered
--------------------	-----------------

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/643581-Conf. #3956
				Filing Date	August 19, 2003
				First Named Inventor	Laurie H. GLIMCHER
				Art Unit	1633
				Examiner Name	Q.J. Li
Sheet	4	of	4	Attorney Docket Number	HUI-041DV

	C59	Yamamura, M. et al. "Local Expression of Antiinflammatory Cytokines in Cancer" <i>J. Clin. Invest.</i> 91:1005-1010 (Mar 1993)	
	C60	Yoshimura, T. et al. "Multiple cDNA clones encoding nuclear proteins that bind to the <i>tax</i> -dependent enhancer of HTLV-1: all contain a leucine zipper structure and basic amino acid domain" <i>EMBO J.</i> 9(8):2537-2542 (1990)	
	C61	European Search Report for Application No. 05013817.1-2401, dated March 17, 2006	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--